



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1051]

Modified Risk Tobacco Product Applications for Snus Products Submitted by Swedish Match North America Inc.; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is reopening the period for public comment on modified risk tobacco product applications (MRTPAs) for specific General Snus products submitted by Swedish Match North America Inc. and announcing the availability for public comment of a recently received amendment to the MRTPAs. The original notice of availability for the applications appeared in the *Federal Register* of August 27, 2014.

In that notice, FDA requested comments on the originally filed MRTPAs that are posted on <https://www.regulations.gov> and FDA's website. In the *Federal Register* of July 31, 2015, FDA issued a notice to reopen and extended the comment period for comments on amendments to the MRTPAs. That comment period closed on August 31, 2015. FDA is now reopening the comment period to seek comment specifically on a recent amendment to the MRTPAs.

DATES: Electronic or written comments on the application may be submitted beginning [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. FDA will establish a closing date for the comment period as described in section I.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2014-N-1051 for “Modified Risk Tobacco Product Applications for Snus Products Submitted by Swedish Match North America Inc.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paul Hart, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002, 1-877-287-1373, email: AskCTP@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of August 27, 2014 (79 FR 51183), FDA published a notice of availability for MRTPAs submitted by Swedish Match North America Inc. and gave the public 180 days to comment on the applications. FDA subsequently published a notice in the *Federal Register* of July 31, 2015 (80 FR 45661), to reopen and extend the comment period to allow for comment on amendments to the applications. The comment period closed on August 31, 2015. On December 14, 2016, FDA issued a letter to Swedish Match North America Inc. that denied the MRTPAs, in part, and outlined deficiencies in the remaining portions of the MRTPAs that the applicant could address by submitting an amendment to the applications. FDA recently received an amendment to Swedish Match North America Inc.'s MRTPAs and is making the amendment available (except for matters in the amendment that are trade secrets or otherwise confidential commercial information) for public comment. FDA is reopening the period for public comment so that the public has the opportunity to review and comment on the amendment.

FDA is required by section 911(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387k(e)) to make an MRTPA available to the public (except for matters in the application that are trade secrets or otherwise confidential commercial information) and to request comments by interested persons on the information contained in the application and on the label, labeling, and advertising accompanying the application. The determination of whether

an order is appropriate under section 911 of the FD&C Act is based on the scientific information submitted by the applicant as well as the scientific evidence and other information that is made available to the Agency, including through public comments.

FDA has posted the application amendment for public comment, which has been redacted in accordance with applicable laws. FDA intends to establish a closing date for the comment period that is at least 30 days after the final documents from the application are made available for public comment and will announce the closing date at least 30 days in advance. FDA will notify the public about the availability of additional application documents, if any, and the closing date for the comment period via the Agency's web page for the MRTPA (see section II) and by other means of public communication, such as by email to individuals who have signed up to receive email alerts. FDA does not intend to issue additional notices in the *Federal Register* regarding amendments or the comment period for these MRTPAs. To receive email alerts, visit FDA's email subscription service management website (<http://go.fda.gov/subscriptionmanagement>), provide an email address, scroll down to the "Tobacco" heading, select "Modified Risk Tobacco Product Application Updates", and click "Submit". To encourage public participation consistent with section 911(e) of the FD&C Act, FDA is making the redacted MRTPAs that are the subject of this notice available electronically (see section II).

II. Electronic Access

Persons with access to the internet may obtain the documents at either <https://www.fda.gov/TobaccoProducts/Labeling/MarketingandAdvertising/ucm533454.htm> or <https://www.regulations.gov>.

Dated: October 23, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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